

Application No. 09/593,591
Reply dated September 30, 2009
Reply to Office Action of April 1, 2009

REMARKS

In the Office Action, the Examiner rejected claims 1, 2, 4, 5, 7-20, 22-30, 32-42, 85, 86, 88, 89, 91-129, 148-152, 155-164, 166, 168-182, 203, 204, 206, 208-224, 226, 228-242, 263, 264, 266, and 268-300 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. As an alternative to the Section 112, first paragraph rejection, the Examiner objected to the specification under 37 C.F.R. § 1.75 (d) (1) as failing to provide proper antecedent basis for the claimed subject matter.

The MPEP sets forth that "[a]n applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 ('drawings alone may provide a 'written description' of an invention as required by Sec. 112*')." (MPEP, § 2163, page 2100-178, col. 2.)

Applicant submits that FIG. 10 as originally filed in this application is sufficiently detailed to show the following features of Applicant's claimed invention: (1) opposite exterior sides of the implant having "straight portions that are generally parallel to each other;" (2) "maximum width [of the opening] transverse to the mid-longitudinal axis" of the body of the implant; (3) the "first dimension" and the "second dimension" and their relative lengths; (4) a "plane perpendicular to and bisecting the length of said body into two parts of equal maximum length along the mid-longitudinal axis . . . the plane passing through at least a portion of said opening;" and (5) the trailing end having a "non-linear portion between two lines parallel to the mid-longitudinal axis." Thus, it is submitted that as required by 35 U.S.C. § 112, first paragraph, Applicant's specification describes the claimed invention in such a way as to reasonably convey to one skilled in the art that Applicant was in possession of the claimed invention.

Moreover, "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." (See MPEP § 2163, page 2100-184, col. 1.) The MPEP further sets forth that "[i]n rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which

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support the lack of written description conclusion." (MPEP § 2163, page 2100-185, col.

1.) Applicant respectfully submits that the Examiner has not met this burden by a preponderance of the evidence as set forth in MPEP § 2163.

37 C.F.R. § 1.75 (d) (1) sets forth that the "claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." As discussed above, FIG. 10, which was part of the specification as originally filed, provides clear support to the claim terms objected to by the Examiner. Accordingly, Applicant submits that the meaning of the claim terms objected to by the Examiner may be ascertainable by reference to at least FIG. 10 of the specification.

The Examiner rejected claims 1, 2, 4, 5, 7-12, 14, 16, 85, 86, 88, 89, 91-96, 98, 100, 102-105, 116, 117, 163, 164, 166, 168-173, 175, 179, 180, 203, 204, 206, 208, 209, 211, 213, 215, 223, 224, 228, 229, 231, 233, 235, 239, 240, 263, 264, 266, 268, 269, 271, 273, 275, 279, and 280 under 35 U.S.C. § 103(a) as obvious over WIPO Publication No. WO 98/17209 to Pafford et al. ("Pafford") in view of U.S. Patent No. 5,861,041 to Tienboon ("Tienboon") or WIPO Publication No. WO 99/08627 to Gresser et al. ("Gresser") or U.S. Patent No. 5,607,4245 to Tropiano ("Tropiano"); and rejected claims 1, 2, 4, 5, 7-20, 22, 25, 30, 32-35, 85, 86, 88, 89, 91-106, 109, 114-119, 127-129, 148, 158, 163, 164, 171, 174, 175, 179, 180, 203, 204, 206, 208-211, 213-215, 219, 220, 223, 224, 226, 228-231, 233-235, 239, 240, 263, 264, 266, 268-271, 273-275, 279, 280, 285, 288, 291, 294, 297, and 300 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,277,149 to Boyle et al. ("Boyle") in view of Tienboon or Gresser or Tropiano. Applicant respectfully traverses the rejections on the ground that none of the combinations proposed by the Examiner teaches or suggests each and every recitation of Independent claims 1, 85, 163, 203, 223, and 263.

Independent claims 1, 85, 163, 203, 223, and 263 recite an interbody spinal fusion implant having a body and an opening coincident with the medullary canal, "said opening having a first dimension as measured on the mid-longitudinal axis of said body between

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the perimeter of said opening toward said leading end of said body and a plane perpendicular to and bisecting the length of said body into two parts of equal maximum length along the mid-longitudinal axis, said opening having a second dimension as measured on the mid-longitudinal axis of said body between the perimeter of said opening toward said trailing end of said body and the plane, said first dimension being greater than said second dimension."

The Examiner admitted that "Pafford is not considered meeting the limitation requiring the distance of first dimension being greater than the second dimension as claimed." (Office Action, page 4, line 22 through page 5, line 1.) The Examiner further admitted that Boyle does not disclose "the majority of the opening being towards the leading end as claimed." (Office Action, page 5, line 21 through page 6, line 1.) The Examiner contended that "Tienboon (see Figure 11) or Gresser (see Figure 1A) or Tropiano (see Figure 4) each suggest that it was known to make openings in spinal implants that are off center and closer to a leading edge than to a trailing edge." (Office Action, page 5, lines 1-3; page 6, lines 9-11.)

In the implant of FIG. 11 of Tienboon, a plane bisecting the length of the implant between the leading and trailing ends does not pass through the opening, and the entire opening is between the bisecting plane and the trailing end (132) of the implant. Thus, the opening of Tienboon does not include a "first dimension" as recited in independent claims 1, 85, 163, 203, 223, and 263. FIG. 1A of Gresser shows that the "second dimension" of opening (19) of implant 10 is greater than the "first dimension." Similarly, for the single opening (18) through which a plane bisecting the length between the leading (14) and trailing (15) ends would pass, the "second dimension" is greater than the "first dimension." FIG. 4 of Tropiano shows that a plane bisecting the length into two parts of equal maximum length would not pass through two of the openings. Thus, each of these openings would not include either the "first dimension" or a "second dimension" as recited in independent claims 1, 85, 163, 203, 223, and 263. In the central opening of FIG. 4 of Tropiano, the "second dimension" is greater than the "first dimension."

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Applicant submits that none of Tienboon, Gresser, and Tropiano discloses or suggests the above-quoted recitation of independent claims 1, 85, 163, 203, 223, and 263. Thus, if either Pafford or Boyle were to be combined with Tienboon or Gresser or Tropiano as proposed by the Examiner, the combination would not result in an implant embodying each and every recitation of independent claims 1, 85, 163, 203, 223, and 263. Accordingly, Applicant submits that the Examiner's rejections of independent claims 1, 85, 163, 203, 223, and 263 and claims dependent therefrom under 35 U.S.C. § 103(a) have been overcome.

The Examiner rejected claims 26-29, 110-113, 149-152, 159-162, 172, 177, 178, 182, 212, 217, 218, 222, 232, 237, 238, 242, 272, 277, 278, and 282 under 35 U.S.C. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano as used in the previous rejection, further in view of U.S. Patent No. 5,397,362 to Kozak et al. ("Kozak"); rejected claims 36-42, 120-126, 166, 168-170, 173, 181, 206, 221, 241, and 281 under 35 U.S.C. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano as applied in the rejection of claim 1 above in further view of the suggestions of Boyle; rejected claims 23, 24, 107, 108, 176, 216, 236, and 276 under 35 U.S.C. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano as applied against claim 1 above, further in view of U.S. Patent No. 5,669,909 to Zdebllick et al. ("Zdebllick"); and rejected claims 283, 284, 286, 287, 289, 290, 292, 293, 295, 296, 298, and 299 under 35 U.S.C. § 103(a) as being unpatentable over Boyle in view of Tienboon. Applicant submits that the rejections of claims 23, 24, 26-29, 36-42, 107, 108, 110-113, 120-126, 149-152, 159-162, 166, 168-170, 172, 173, 176-178, 181, 182, 206, 212, 216-218, 221, 222, 232, 236-238, 241, 242, 272, 276-278, 281-284, 286, 287, 289, 290, 292, 293, 295, 296, 298, and 299 are rendered moot at least because these claims depend from an allowable independent claim, or claims dependent therefrom.

Applicant submits that independent claims 1, 85, 163, 203, 223, and 263 are patentable and that dependent claims 2, 4, 5, 7-20, 22-30, 32-42, 86, 88, 89, 91-129, 148-152, 158-162, 164, 166, 168-182, 204, 206, 208-222, 224, 226, 228-242, 264, 266, and 268-300, dependent from one of independent claims 1, 85, 163, 203, 223 and 263,

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or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

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